Zai Lab Announces Acceptance of sNDA Submission of ZEJULA® (Niraparib) for First-Line Maintenance Treatment of Ovarian Cancer in China by the NMPA

March 16, 2020

SHANGHAI, China and SAN FRANCISCO, March 16, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced the China National Medical Products Administration (NMPA) has accepted its supplemental New Drug Application (sNDA) for ZEJULA® (niraparib) as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

"We believe ZEJULA is a potential best-in-class PARP inhibitor due to its compelling efficacy, once-daily dosing and superior pharmacokinetic properties including its ability to cross the blood brain barrier," said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. "The NMPA's acceptance of our sNDA submission for ZEJULA as a first-line monotherapy treatment after surgery and platinum-based chemotherapy has the potential to both fundamentally change how women with ovarian cancer are treated in China and significantly expand ZEJULA's market opportunity. Zai Lab remains committed to make a meaningful impact on the way cancer is treated in China and globally, and we plan to continue to develop and bring many new and innovative treatment options to patients in need."

The PRIMA study conducted by our partner GlaxoSmithKline plc (GSK) demonstrated that ZEJULA treatment resulted in a 38% reduction in the risk of disease progression or death in the overall study population when compared to placebo. ZEJULA also demonstrated benefits in all patient subgroups. For patients whose cancer is associated with homologous recombination deficiency (HRD) positive status, ZEJULA treatment resulted in a 57% reduction in the risk of disease progression or death.

GSK submitted a sNDA to the U.S. FDA for the use of ZEJULA in ovarian cancer as first-line maintenance treatment based on the PRIMA study, and the application was accepted in February 2020 and is being reviewed under the Real-Time Oncology Review (RTOR) pilot program.

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic cancers in China with more than 52,000 newly diagnosed cases and 23,000 deaths each year. While platinum-based chemotherapy is effective at inducing an initial response in ovarian cancer, the disease will recur in the majority of women. New agents that prolong the duration of response following platinum-based treatment and delay the inevitable relapse of ovarian cancer will benefit patients with ovarian cancer in China.

About ZEJULA (niraparib)

ZEJULA (niraparib) is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. The NMPA recently accepted Zai Lab's sNDA for niraparib is a monotherapy maintenance treatment in adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

Zai Lab has ongoing pivotal studies in Chinese patients for first-line and second-line maintenance therapies in ovarian cancer. Zai Lab also conducted a Phase 1 pharmacokinetic (PK) study of niraparib in Chinese patients with ovarian cancer. This study was published in August 2019 in The Oncologist and demonstrated that the PK profile of niraparib in Chinese patients were comparable to that of patients evaluated in ZEJULA's global PK study.

Zai Lab in-licensed rights to ZEJULA from GSK for Mainland China, Hong Kong and Macau. The NDA for recurrent ovarian cancer was accepted by the NMPA on December 12, 2018, granted priority review status on January 29, 2019 and approved on December 27, 2019. Zai Lab has obtained approvals to market ZEJULA in Mainland China, Hong Kong and Macau for maintenance therapy in patients with platinum-sensitive, recurrent ovarian cancer.

Since the Hong Kong launch of ZEJULA in October 2018, it has rapidly gained market share in the region despite being launched more than two years behind Lynparza®. Based on IQVIA (formerly IMS) data, ZEJULA is now the market leading PARP inhibitor with market share in Hong Kong of 71% for the full year ended December 31, 2019.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a China and U.S.-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the potential for ZEJULA to be a best-in-class PARP inhibitor, plans for commercializing niraparib in China, the potential for ZEJULA to both fundamentally change how women with ovarian cancer are treated in China and significantly expand ZEJULA's market opportunity and other statements containing words such as "anticipates", “believes”, "expects", “plan” and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) Zai Lab’s ability to obtain additional future funding, (2) Zai Lab’s results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab’s drug candidates, (4) Zai Lab’s ability to generate revenue from its drug candidates, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2018 and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab’s expectations and assumptions to change and undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing Zai Lab’s views as of any date subsequent to the date of this press release.

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